

Attorney Docket No.: PTQ-0058  
Inventors: Van Eyk et al.  
Serial No.: 10/824,027  
Filing Date: April 14, 2004  
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REMARKS

Claims 1 and 13-20 are pending in the instant application. Claims 1 and 13-20 have been rejected. Claims 1 and 13-20 have been amended. Support for these amendments is provided in the specification at page 13, lines 12-17 and page 14, lines 35-36. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims under 35 U.S.C. 102(b)

The rejection of claims 1, 13 and 14 under 35 U.S.C. 102(b) as being anticipated by Mochly-Rosen (U.S. Patent 6,165,977) has been maintained. The Examiner suggests that Mochly-Rosen discloses the use of  $\epsilon$ PKC to screen for compounds effective to induce preconditioning in a cell. The Examiner suggests that activation of  $\epsilon$ PKC requires  $Ca^{2+}$  ions, and therefore it is being interpreted to be a  $Ca^{2+}$  handling protein.

Applicants respectfully traverse this rejection.

Contrary to the Examiner's suggestion,  $\epsilon$ PKC is a novel PKC isoform which is not activated by calcium. Applicants are submitting herewith a 1999 review paper by Michael

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Gschwendt (Eur. J. Biochem. 1999 259:555-564) which makes clear that  $\epsilon$ PKC is  $Ca^{2+}$ -independent (see Abstract).

Thus, since Mochly-Rosen does not teach any of the claimed preconditioning proteins, this reference does not teach all the elements of the claim as required to anticipate the instant claimed invention. See MPEP 2131.

Withdrawal of this rejection under 35 U.S.C. 102(b) is therefore respectfully requested.

## II. Objection to Claim 16

Claim 16 has been objected to for including the abbreviation IDH.

Accordingly, in an earnest effort to advance the prosecution of this case, claim 16 has been amended to spell out this abbreviation. Support for this amendment is provided in the specification at page 14, lines 35-36.

Withdrawal of this objection is therefore respectfully requested.

## III. Rejection of Claims 1 and 16-18 under 35 U.S.C. 112, second paragraph

Claims 1 and 16-18 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

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particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, with respect to claim 1, the Examiner suggests that it is unclear what is being modulated and what Ca<sub>2+</sub> handling protein describes.

Applicants respectfully disagree.

MPEP § 2173.02 states that definiteness of claim language must be analyzed not in a vacuum, but in light of: (A) the content of the particular application; (B) the teachings of the prior art; and (C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

The term "modulate" is defined at page 14, lines 8-15 of the specification. This definition in the specification makes clear what is being modulated and further clarification in the claims should not be required.

Applicants believe what is meant by Ca<sub>2+</sub> handling protein is also clear from teachings in the specification beginning at page 17 and extending to page 19. Further clarification of this term in the claims should also not be required.

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Further, with respect to claims 16, 17 and 18, the Examiner suggests that it is unclear what is meant by levels. Specifically, the Examiner suggests that level could be referring to biological activity or steady state quantity of the protein.

Applicants believe that the term "level" meaning quantity as opposed to activity is also clear from all data and experimental methodologies presented in the patent application. See, for example, the Examples and Figures which describe methods and present data relating to quantity of a protein.

However, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to state that abundance of the protein is modulated. Further, in claims 16, 17 and 18, Applicants have replaced the term "level" with --abundance--. Support for this amendment is provided at page 13, lines 12-17 of the instant specification.

Withdrawal of these rejections is therefore respectfully requested.

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**IV. Rejection of Claims 1, 13, 14, 15, 16, 19 and 20 under 35 U.S.C. 102(b)**

Claims 1, 13, 14, 15, 16 and 20 have been rejected under 35 U.S.C. 102(b) as being anticipated by Currie et al. (Brain Research 863:169-181 (2000)). The Examiner suggests that Currie et al. disclose an event capable of preconditioning brain tissue.

Claims 1, 13, 14, 15, 16, 19 and 20 have also been rejected under 35 U.S.C. 102(b) as being anticipated by Kobara et al. (J. Mol. Cell Cardiol. 28:417-428). The Examiner suggests that Kobara et al. disclose an experimental protocol that compares the effects of preconditioning on mitochondrial oxidative phosphorylation pathway protein, ATPase and adenine nucleotide translocase. The experimental protocol involves the event of clamping the aortic line for two cycles of a 5 minute period of global ischemia followed by 5-minute period of reperfusion.

It is respectfully pointed out that neither of these references teach or suggest methods for identifying an agent which is capable of priming a cell for preconditioning and/or inducing preconditioning of a cell, tissue or organ. Instead, both references simply summarize effects of an established preconditioning event.

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Accordingly, in an earnest effort to distinguish the present invention from these teachings, Applicants have amended the claims to delete the phrase "or event". Since neither of the cited reference teach a method for identifying an agent capable of priming a cell for preconditioning and/or inducing preconditioning of a cell, tissue or organ which comprises assessing the ability of the agent to modulate abundance of a preconditioning protein in a cell, tissue or organ by detecting a modulation in abundance of the preconditioning protein in the presence of the agent as compared to the abundance of preconditioning protein in the absence of the agent, wherein the preconditioning protein is a protein of an oxidative phosphorylation (OxPhos) pathway, tricarboxylic acid (TCA) cycle, a  $\text{Ca}^{2+}$  handling protein, a chaperone protein, or a protein selected from aldehyde dehydrogenase, NG-dimethylarginine dimethylaminohydrolase (DDAH), and the RNA binding protein regulatory subunit DJ-1, these references cannot anticipate the instant claimed invention.

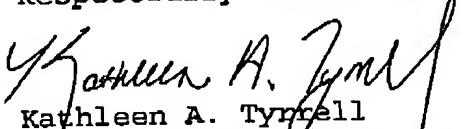
Withdrawal of these rejections under 35 U.S.C. 102(b) is therefore respectfully requested.

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v. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
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